

**IN THE UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF MISSOURI  
WESTERN DIVISION**

JULIE HANIFL,

Plaintiff,

v.

ETHICON, INC., and  
JOHNSON & JOHNSON,

Defendants.

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No. 4:20-cv-00527-DGK

**ORDER DENYING MOTION TO EXCLUDE DEFENDANTS' EXPERTS**

This product-liability case arises out of the implantation of Defendants' TVT-Exact in April 2011 to treat stress urinary incontinence. Plaintiff alleges the device, a pelvic mesh product, caused dyspareunia, a condition causing severe vaginal pain during intercourse. Now before the Court is Plaintiff's motion to exclude certain opinions and testimony of Denise Elser, M.D., an expert witness for Defendants (Doc. 85).

For the following reasons, the motion is DENIED.

**Background**

Plaintiff experienced stress urinary incontinence and, in April 2011 underwent a procedure that included the implantation of TVT-Exact mesh sling. After the implantation, Plaintiff experienced dyspareunia, lower abdominal pain, the recurrence of urinary incontinence, and a variety of emotional and psychological injuries. Plaintiff attributed these injuries to the TVT-Exact. In October 2011, Plaintiff underwent a procedure to remove a portion of the TVT-Exact mesh, but despite the removal, Plaintiff claims her injuries are ongoing.

Defendant Ethicon, Inc. retained Denise Elser, M.D., board-certified in female pelvic medicine and reconstructive surgery, to testify as a case-specific expert. Based on her review of

Plaintiff's medical records, without ever examining Plaintiff herself, Dr. Elser opined that the cause of Plaintiff's pain may be due to a neuroma and cannot be affirmatively determined to be caused by the TVT-Exact. Dr. Elser expanded upon this opinion in her October 2019 deposition.

Plaintiff now seeks to exclude that portion of Dr. Elser's testimony that speaks to the specific cause of Plaintiff's injury.

### **Standard**

When the admissibility of expert testimony is challenged, the district court must make "a preliminary determination of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993). The party seeking to introduce the expert's testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). Under Federal Rule of Evidence 702, reliability may turn on several factors:

- (a) the expert's scientific, technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods;
- and (d) the expert has reliably applied the principles and methods to the facts of the case.

In other words, the proponent must show that the expert's opinions are relevant, the expert is qualified to offer them, and "the methodology underlying [her] conclusions is scientifically valid." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006). Doubts should be resolved in favor of admissibility, *id.* at 758, as Rule 702 is "one of admissibility rather than exclusion." *Arcoren v. United States*, 929 F.2d 1235, 1239 (8th Cir. 1991).

The Court also notes Rule 702 speaks only to its role as gatekeeper. The credibility and weight of testimony is left to the trier of fact. *See, e.g., Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1183 (8th Cir. 1997).

### **Analysis**

Plaintiff seeks to exclude Dr. Elser's case-specific opinion first on the grounds that it is not reliable. Plaintiff claims Dr. Elser offers no explanation for her conclusion and has never before reached the same conclusion. Plaintiff cites to Dr. Elser's deposition testimony where she stated that "without a recent thorough pelvic exam, I just don't know [whether a neuroma at the incision point is the only explanation for her dyspareunia]" (Doc. 85-2 at 32:3–17). Dr. Elser never performed an examination of Plaintiff and testified during her deposition that Plaintiff's symptoms are unique. This uniqueness, argues Plaintiff, makes her opinion without an examination of Plaintiff unreliable.

After reviewing Dr. Elser's expert report, the Court finds her testimony to be the product of sufficiently reliable principles and methods; Plaintiff's complaints speak to the weight and credibility of Dr. Elser's testimony, not its admissibility. Dr. Elser has extensive experience with pelvic mesh products and specific experience with the TVT-Exact mesh at issue. Dr. Elser's opinion was based on her review of Plaintiff's medical records from August 2007 to May 2019. After reviewing Plaintiff's records, Dr. Elser provides an opinion based on her specialized training and experience. In her deposition testimony, the Court finds ample explanation for her suggesting a neuroma as the cause of Plaintiff's pain. The Court finds no reason to exclude an expert opinion merely because it has not been similarly offered in other cases, as Plaintiff requests.<sup>1</sup>

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<sup>1</sup> The MDL Court issued a similar ruling, specifically finding Dr. Elser's testimony to be "sufficiently reliable" and urged plaintiffs to utilize the opportunity presented by cross-examination to show where her opinion may be lacking (Doc. 89-3 at 5). This Court agrees.

Plaintiff also seeks exclusion based on Dr. Elser's lack of proffering a differential diagnosis as to the cause of Plaintiff's dyspareunia, despite later conceding defense experts are not required to provide a full differential diagnosis. (*See* Doc. 89-3 at 4 (citing MDL Court's ruling that defendant experts "do not need to conduct a differential diagnosis to identify the specific cause of an injury because they do not bear the burden of proving causation")). A differential diagnosis "determines all of the possible causes for the patient's symptoms and then eliminates each of these potential causes until reaching one that cannot be ruled out, or deduces which of those that cannot be excluded is the most likely." *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 560 n.2 (8th Cir. 2014). While differential diagnoses are presumptively valid under *Daubert*, it is not required. *Id.* Instead, defendants' expert witnesses are free to suggest alternative causes of a patient's injury and have no duty to rule out all other possible causes of injury. *See id.*; *Kirk v. Schaeffler Group USA, Inc.*, 887 F.3d 376, 392 (8th Cir. 2018); *Lauzon*, 270 F.3d at 693.

Here, Dr. Elser, using her training and experience, offers an alternative cause to Plaintiff's injury in order to rebut the evidence Plaintiff and Plaintiff's expert witnesses offer. Her testimony is the product of sufficiently reliable principles and methods to be admissible under *Daubert*. To the extent Plaintiff disagrees with Dr. Elser's opinion or her explanation of that opinion, such issues are to be addressed on cross-examination.

### **Conclusion**

For the reasons above, Plaintiff's motion is DENIED.

**IT IS SO ORDERED.**

Date: February 18, 2021

/s/ Greg Kays  
GREG KAYS, JUDGE  
UNITED STATES DISTRICT COURT